

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 00786/440WO6	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/US2004/019186	International filing date ( <i>day/month/year</i> ) 16 June 2004 (16.06.2004)	Priority date ( <i>day/month/year</i> ) 16 June 2003 (16.06.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant THE GENERAL HOSPITAL CORPORATION		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).																								
2.	This REPORT consists of a total of 4 sheets, including this cover sheet.  In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 80%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 19 December 2005 (19.12.2005)
Facsimile No. +41 22 740 14 35	Authorized officer <div style="text-align: center; font-weight: bold; margin: 10px 0;">Beate Giffo-Schmitt</div> Telephone No. +41 22 338 87 20

Form PCT/IB/373 (January 2004)

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# PATENT COOPERATION TREATY

REC'D 08 MAR 2005

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From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
KAREN L. ELBING  
CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) **03 MAR 2005**

Applicant's or agent's file reference

00786/440WO6

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

PCT/US04/19186

International filing date (day/month/year)

16 June 2004 (16.06.2004)

Priority date (day/month/year)

16 June 2003 (16.06.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C07H 21/04; C12N15/85,86; C07K14/00+; A01K 67/00 and US Cl.: 536/24.5; 435/325; 530/350+; 800/8

Applicant

THE GENERAL HOSPITAL CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

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Authorized officer

Joanne Hama, Ph.D.

Telephone No. (571) 272-2911

Form PCT/ISA/237 (cover sheet) (January 2004)

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/19186

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US04/19186

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-36</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>27, 35-36</u>	YES
	Claims <u>1-26, 28-34</u>	NO
Industrial applicability (IA)	Claims <u>1-36</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-34 lack an inventive step under PCT Article 33(3) as being obvious over Clayton (2001, Biochemical Society Transactions, 29: 298-305) in view of McKay et al. (2003, Developmental Cell, 4:131-142). At the time of filing, it was well known in the art that there were clinical consequences resulting from defects in peroxisomal  $\beta$ -oxidation (see Clayton). Also, at the time of filing, it was well known in the art that *C. elegans* could be used as a model to examine peroxisomal  $\beta$ -oxidation. McKay et al. teach that that *C. elegans* were used as a system for studying the genetics of fat. The artisans used RNAi against worm SREBP and C/EBP (McKay et al., page 132, 2<sup>nd</sup> col. 2<sup>nd</sup>-3<sup>rd</sup> parag.). The artisans also teach that *lpd* genes were implicated in the mitochondrial respiratory chain (McKay et al., page 134, 2<sup>nd</sup> col., 2<sup>nd</sup> parag.) and that proper mitochondrial respiratory chain function is necessary for lipid accumulation (McKay et al., 136, 1<sup>st</sup> col., 2<sup>nd</sup> parag. to page 137, 1<sup>st</sup> col., 1<sup>st</sup> parag.).

Claim 20, 24 encompasses transgenic humans, which is non-statutory matter.

Claims 1, 2, 4, 7-11, 13, 14, 21, 23 meet the criteria set out in PCT Article 33(2), because the prior art does not teach a method for identifying nucleic acids encoding polypeptides and polypeptides involved in regulating lipid accumulation in *C. elegans*.

Claims 35, 36 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest that there are pharmaceutical compositions comprising either the polypeptide or portion thereof of KAT-1, KAT-2 EGL-4 ALD-1, CHE-2, DAF-6, OSM-5, C29E6.4, TAX-2, and TAX-4. The art also does not teach a nucleic acid molecule or portion thereof, encoding mammalian orthologs of *kat-1*, *kat-2*, *egl-4*, *ald-1*, *che-2*, *daf-6*, *osm-5*, C29E6.4, *tax-2*, and *tax-2*.

Claims 1-36 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.